

**TRANSMITTAL OF INFORMATION DISCLOSURE STATEMENT**

(Under 37 CFR 1.97(b) or 1.97(c))

Docket No.

DI-6121

In Re Application: Martis et al.

Application No.

10/789,320

Filing Date

Feb. 27, 2004

Examiner

Unknown

Customer No.

29200

Group Art Unit

1623

Confirmation No.

9380

Title: **METHODS AND COMPOSITIONS FOR DETECTION OF MICROBIAL CONTAMINANTS IN PERITONEAL DIALYSIS SOLUTIONS**

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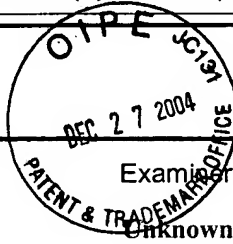
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Application No.	Filing Date	Examiner	Customer No.	Group Art Unit	Confirmation No.
10/789,320	Feb. 27, 2004	Unknown	29200	1623	9380

Title: **METHODS AND COMPOSITIONS FOR DETECTION OF MICROBIAL CONTAMINANTS IN PERITONEAL DIALYSIS SOLUTIONS**

Address to:  
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**37 CFR 1.97(b)**

1. ☒ The Information Disclosure Statement submitted herewith is being filed within three months of the filing of a national application other than a continued prosecution application under 37 CFR 1.53(d); within three months of the date of entry of the national stage as set forth in 37 CFR 1.491 in an international application; before the mailing of a first Office Action on the merits, or before the mailing of a first Office Action after the filing of a request for continued examination under 37 CFR 1.114.

**37 CFR 1.97(c)**

2. ☐ The Information Disclosure Statement submitted herewith is being filed after the period specified in 37 CFR 1.97(b), provided that the Information Disclosure Statement is filed before the mailing date of a Final Action under 37 CFR 1.113, a Notice of Allowance under 37 CFR 1.311, or an Action that otherwise closes prosecution in the application, and is accompanied by one of:

☐ the statement specified in 37 CFR 1.97(e);

**OR**

☐ the fee set forth in 37 CFR 1.17(p).



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Martis et al.  
Appl. No.: 10/789,320  
Conf. No.: 9380  
Filed: February 27, 2004  
Title: METHODS AND COMPOSITIONS FOR DETECTION OF MICROBIAL  
CONTAMINANTS IN PERITONEAL DIALYSIS SOLUTIONS  
Art Unit: 1623  
Examiner: Unknown  
Docket No.: DI-6121 (BBL No. 112713-535)

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

INFORMATION DISCLOSURE STATEMENT

Sir:

In accordance with the provisions of 37 C.F.R. 1.56, 37 C.F.R. 1.97, and 37 C.F.R. 1.98, Applicants request that a citation and examination of the references cited below, and on the attached PTO-1449 form, be made during the course of examination of the above-identified application for United States patent. Pursuant to the Official Gazette Notice dated August 5, 2003, copies of the cited U.S. patents and patent applications are not included as this application was filed after June 30, 2003. However, copies of all other cited references are included with this form.

**U.S. PATENT DOCUMENTS**

<u>Document No.</u>	<u>Date</u>	<u>Inventor</u>
4,761,237	08/02/88	Alexander et al.
4,886,789	12/12/89	Milner
4,970,152	11/13/90	Ashida et al.
5,431,496	07/11/95	Balteau et al.
6,077,836	06/20/00	Milner
6,248,726	06/19/01	Alsop et al.
6,770,148	08/03/04	Naggi et al.
2004/0121982	06/24/04	Martis et al.

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Karanicolas et al., "Epidemic of aseptic peritonitis caused by endotoxin during chronic peritoneal dialysis," *N Engl J Med* 1977;296:1336-7

Mangram et al., "Outbreak of sterile peritonitis among continuous cycling peritoneal dialysis patients," *Kidney Int* 1988;54:1367-71

Smith et al., "Chemical peritonitis associated with intraperitoneal vancomycin," *Ann Pharm* 1991;25:602-3

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Wilkie et al., "Icodextrin 7.5% dialysate solution (glucose polymer) in patients with ultrafiltration failure: extension of technique survival," *Perit Dial Int* 1997;17:84-7

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- Sriskandan et al., "Gram-positive sepsis," *Bacterial Sepsis and Septic Shock*, Philadelphia: W. B. Saunders Company, 1999:397-412
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- Schwab, John, "Phlogistic properties of peptidoglycan-polysaccharide polymers from cell walls of pathogenic and normal flora bacteria which colonize humans," *Infect Immun* 1993;61:4535-9
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- Burke et al., "Direct determination of polyglucose metabolites in plasma using anion-exchange chromatography with pulsed amperometric detection," *J Chromatogr B* 1997;693:353-7
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- Inada et al., "A silkworm larvae plasma test for detecting peptidoglycan in cerebrospinal fluid is useful for the diagnosis of bacterial meningitis," *Microbiol. Immunol.*, 47(10), 701-707, 2003
- Tsuchida et al., "Detection of peptidoglycan and endotoxin in dialysate, using silkworm larvae plasma and limulus amebocyte lysate methods," *Nephron* 1997, 75, 438-443
- Silkworm Larvae Plasma, 73, 1999, 1222-1226

Applicants look forward to early and favorable consideration of this matter.

Respectfully submitted,

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Dated: December 23, 2004

<b>INFORMATION DISCLOSURE CITATION</b> <b>IN AN APPLICATION</b> (Use several sheets if necessary) PTO Form 1449	Atty Docket No. DI-6121	Application No. 10/789,320
	Applicant Martis et al.	
	Filing Date Feb. 27, 2004	Group 1623

U.S. PATENT DOCUMENTS							
Examiner's Initials	Document Number	Publication Date	Inventor	Class	Subclass	Filing Date If Appropriate	
	4,761,237	08/02/88	Alexander et al.				
	4,886,789	12/12/89	Milner				
	4,970,152	11/13/90	Ashida et al.				
	5,431,496	07/11/95	Balteau et al.				
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	6,248,726	06/19/01	Alsop et al.				
	6,770,148	08/03/04	Naggi et al.				
	2004/0121982	06/24/04	Martis et al.				

FOREIGN PATENT DOCUMENTS							
Examiner's Initials	Document Number	Publication Date	Country	Class	Subclass	Translation	
						Yes	No

Examiner's Initials	OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)
	Vas, Stephen "Peritonitis," <i>Peritoneal Dialysis</i> . 3 <sup>rd</sup> ed. Dordrecht, The Netherlands: Kluwer Academic Publishers, 1989:261-84.
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